



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 27, 1999

Eric M. Mittleberg, Ph.D.
Vice President-Scientific Affairs
Zenith Goldline Pharmaceuticals
4400 Biscayne Blvd.
Miami, FL 33137

Dear Dr. Mittleberg:

Your petition requesting the Food and Drug Administration (FDA) to refrain from approving abbreviated new drug applications for clozapine until the FDA develops standards and procedures for patient registries was received by this office on May 25, 1999. It was assigned docket number 99P-1652/CP 1 and it was filed on May 27, 1999. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

79P-1652

ACK 1